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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,415	05/16/2001	Falk Fish	FISH4	9137

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/763,415	FISH, FALK	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed January 8, 2003 has been entered. The examiner acknowledges the amendment to the specification. Claim 9 has been amended. Claims 1-12 are under consideration in the office action.

Withdrawal of Rejections

2. The rejection of claims 4-5 and 9 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants' amendments and arguments.

Response to Arguments

3. Applicant's arguments, filed January 8, 2003 with respect to the rejections of claim(s) 1-12 have been fully considered however the arguments are not persuasive for the following reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record. The rejection was on the grounds that the specification,

while being enabling for a method for determining the level of glucose and hemoglobin in a sample obtained from a hair follicle, saliva or urine from an individual comprising: obtaining a sample from the individual; wherein the hair sample is washed and incubated in red cell lysing agent; two aliquots of sample are prepared: sample A is used to determine the level of glucose in the obtained blood or interstitial fluid after it is mixed with glucose oxidase, horseradish peroxidase and luminol and then placed in a luminometer which detects the amount of luminescence while sample B is used to determine the level of hemoglobin in the blood and interstitial fluid obtained from the hair sample as determined by the luminometer and finally the levels of glucose and hemoglobin in the sample are calculated using the net glucose reaction, does not reasonably provide enablement for a method for determining the level of an analyte in the blood of an individual comprising: obtaining a sample from an individual, said sample being a non-blood sample but containing blood components; determining the volume of blood in the obtained sample by measuring the level of a blood component in said sample; determining the amount of glucose in the sample or in the blood cells present in the sample and calculating the level of glucose in the sample.

Applicant asserts that there is no reasons to believe that one skilled in the art would not be able to analyze the existence of any analyte whose presence in a non-blood sample may attest to its existence in blood. Applicant has also submitted ANNEX A to demonstrate the analysis of different analytes.

However, it is the examiner's position that determining the existence of an analyte in a sample is not equivalent to determining the level of analyte in the blood of

an individual by the claimed method. The references are insufficient to overcome the rejection of claims based upon insufficiency of disclosure under 35 USC 112, first paragraph. The supplied references do not teach determining the volume of blood in the sample; determining the amount of analyte in the sample or in the blood cells present and calculating the level of analyte in the blood of the individual. Neither do the references state that undue experimentation will not be required ~~for test~~ for the determination of any type of analyte by the claimed method. Furthermore, it is noted that all the references are drawn to glycosylation products, thus the scope of the references is significantly smaller when compared to the breadth of the claims. The references A-E state opinions about ~~glycoslaytio~~glycosylation products in hair strands or hair proteins without any reference to the determination of non-glycosylation analytes or other sample sources. References F-J refer to saliva as a diagnostic tool, yet none of the references determine the level of analyte using the claimed determination steps. It is noted that none of the references use saliva sample to detect any glycosylation products, likewise none of the hair samples teach assessing the level of lithium in the claimed manner. Furthermore, Reference I states that using saliva samples can create great variability in the determination of lithium levels depending on the age of the individual. Therefore the art teaches great variability in the analysis, which would lead to unexpected results requiring undue experimentation. Thus the supplied references fail to support applicants' assertion that one skilled in the art could determine the level of analyte in the blood of an individual by the claimed method.

Applicants' assert that there is a correlation between concentrations of glucose in hair and in the blood. However, in response to applicant's argument, it is noted that the features upon which applicant relies i.e., the correlation of glucose on hair and in blood are not recited in the rejected claims. The claims are significantly broader and encompass the determination any analyte from any type of sample. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specification, ~~teach~~ teaches the determination of the level of glucose and hemoglobin in a sample obtained from a hair follicle, urine or saliva using a luminescent method or lysis method, but the specification does not teach how to determine the level of any analyte in the blood. The claims broadly recite determining the level of any analyte in the blood in any type of non-blood sample and correlating the level of that analyte found in the sample to the level of analyte in the blood. However, neither the claims nor the specification recite method steps determining the level of every possible analyte from non-blood samples. Furthermore, there is no teaching that the level of analyte found in the sample correlates to the amount of analyte found in the blood of an individual. Finally, the instant claims fail to recite all of the necessary method steps and reagents required to determine the level of glucose and hemoglobin in the sample. Therefore, the claims are not enabled for a method for determining the level of an analyte in the blood of an individual.

Applicants urge that claim 4 claims a method of indirectly ~~determine~~ determining the amount of analyte, specifically glucose in either interstitial fluid or blood obtained from the hair sample and comparing the total amount of interstitial fluid or blood from which the glucose was extracted.

However, claim 4 is limited to indirectly determining glucose levels or concentration amount. Steps (ii) and (iii) alternatively claim determining levels in interstitial fluid, yet step (iv) recites calculating the level of analyte in the blood of the tested individual. Applicant has not clarified how a skilled artisan can use only determinations of interstitial fluid to calculate or compare the level of analyte in the tested blood of an individual. Thus, there is no teaching of how to determine the level of analyte in the blood after determining level and concentration in interstitial fluid. The specification fails to provide guidance on such methods, thus in view of the unpredictability for determining the level of analyte in blood based on the determination of interstitial fluid, one skilled in the art could not use the broadly claimed invention without undue experimentation. Therefore, applicants' assertions are not persuasive.

Applicants urge that Ben-Aryeh et al., does not teach determining glucose from samples by way of correcting the glucose measurement by the measurement of hemoglobin or relating the determination of glucose in the interstitial fluid which may be separated from saliva.

In response to applicant's argument about Ben-Aryeh et al., it is noted that for enablement the test is not like the test for obviousness. The test is not whether the features of the reference bodily incorporate the claimed method; nor is it whether that

the claimed invention must be expressly suggested in any one or all of the references. Therefore, Ben-Aryeh et al., does not need to teach all the aspects of the claimed invention.

It is the examiner's position that applicants have no support that the determination of glucose levels in saliva will correlate with the level of analyte in the blood of the donor. Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broad claimed invention without undue experimentation. Thus, one of skill in the art would have to locate de novo steps required for a method of determining the level of any analyte including glucose in the blood of the sample donor. There is no guidance as to what analytes, besides glucose, can be analyzed using this method. The art teaches away from using determined glucose levels in saliva to determine the level of analyte in the blood of a donor. Moreover, there is no requirement for the use of detectable reagents that would determine the level of glucose or analyte in a sample. Given the lack of guidance contained in the specification and the unpredictability for determining the level of analyte in the blood an individual, based upon determining the amount of analyte in the non-blood sample, one skilled in the art, could not use the broadly claimed invention without undue experimentation. Therefore in view of reasons stated above, the rejection is maintained.

5. The rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained.

Applicants assert that there is no need to recite specific steps. However, it is the examiner's position that the claims fail to specifically state what measurement techniques are being employed. Merely stating that determination will occur without describing the steps is inadequate. There is no recitation of how the analyte will be measured. There is no contact step wherein the sample is contacted with the reagents required to determine the volume or amount of blood or analyte; there is no detection step which detects the volume or amount of blood and analyte; there is no correlation step which correlates determining the amount of analyte and blood in a sample to the level of analyte in the blood of the sample donor. The claims must positively recite method steps. In view of the omission, the claim amounts to gaps between the steps since there is no contacting step or detection step that would enable the measurement of analyte from a sample. Therefore, in view of the lack of described steps the rejection is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines
March 18, 2003

LYNETTE F. SMITH
SUPERVISORY PATENT EXAMINER
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